

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE FLONASE ANTITRUST	:	
LITIGATION	:	CIVIL ACTION
	:	No. 08-3301
THIS DOCUMENT RELATES	:	
TO:	:	
Indirect Purchaser Actions	:	
	:	

MEMORANDUM

December 21st, 2015

ANITA B. BRODY, J.

More than a year after I approved a Settlement Agreement between indirect purchasers of the prescription drug Flonase¹ and its generic equivalents, and GlaxoSmithKline (“GSK”), Louisiana’s Attorney General filed a lawsuit against GSK seeking to recover for purchases of the drug made by the State of Louisiana. GSK moves to enforce the Settlement Agreement and to enjoin Louisiana from maintaining any claim against GSK that is covered by the Settlement Agreement. Louisiana, in turn, moves to dismiss for lack of jurisdiction or to stay GSK’s motion. Because Louisiana has not waived its sovereign immunity and consented to this Court’s jurisdiction, I will grant Louisiana’s Motion to Dismiss (ECF No. 667) and deny GSK’s Motion to Enforce Class Settlement (ECF No. 661).

I. BACKGROUND

This litigation arises from allegations that GSK illegally delayed the introduction of a cheaper, generic version of Flonase by filing sham citizen petitions with the Food & Drug

¹ Flonase is the brand-name version of fluticasone propionate (“FP”), a nasal corticosteroid used to treat nasal inflammation caused by allergies.

Administration (“FDA”), resulting in overcharges to indirect purchasers of the drug. After vigorous settlement negotiations, the parties reached a Settlement Agreement in November 2012 under which GSK agreed to pay \$35 million to indirect purchasers of fluticasone propionate (“FP”) in exchange for the settlement and release of all of their claims. *See ECF No. 566, Ex. 1,* at 8.

A. Preliminary Approval of the Settlement and Notice Plan

On January 14, 2013, I “conditionally” certified² the following class for settlement purposes under Federal Rule of Civil Procedure 23(b)(3) (“Settlement Class”):

All persons throughout the United States and its territories who purchased and/or paid for, in whole or in part fluticasone propionate nasal spray, whether branded Flonase or its AB-rated generic equivalents, intended for the consumption of themselves, their family members and/or household members, and all Third Party Payor entities throughout the United States and its territories that purchased, paid for, administered and/or reimbursed for fluticasone propionate nasal spray, whether branded Flonase or its generic equivalents, intended for consumption by their members, employees, plan participants, beneficiaries or insureds,

The applicable time period for the Settlement Class is May 19, 2004 through March 31, 2009.

Third Party Payors are all health insurance companies, healthcare benefit providers, health maintenance organizations, self-funded health and welfare plans, and any other health benefit provider and/or entity that contracts with a health insurer acting as a third party administrator to administer their prescription drug benefits.

ECF No. 570, at 4. The Settlement Class excluded:

the United States and/or State governments and their agencies and departments, except to the extent they purchased fluticasone propionate nasal spray (branded Flonase and/or its generic

² Presently, in the Third Circuit, the appropriate term for this step is a “preliminary determination regarding class certification.” *In re Nat'l Football League Players Concussion Injury Litigation*, 775 F.3d 570, 584 (3d Cir. 2014) (internal quotation marks omitted); *see id.* (noting that “‘conditional certification’ should not be a preferred term of art in this Circuit”)

equivalents) for their employees or others covered by a government employee health plan.

Id.

I also preliminarily approved the Settlement Agreement reached by the parties and approved their proposed Notice Plan. Under this Notice Plan, Class Counsel was responsible for mailing a postcard Settlement Notice “to each third-party payor Settlement Class member . . . who can be identified through reasonable effort.” *Id.* at 6. Class Counsel was also required to publish “the summary notice available to the rest of the Class” in several publications. *Id.* at 7. Any class member who requested a long-form Settlement Notice would be sent one by mail. *Id.* The Settlement Notices informed the recipients of their potential membership in the Settlement Class, the terms of the Settlement Agreement, their right to object or opt out of the settlement, and the consequences of failing to opt out. *See id.*, Attachs. 1-4.

In addition to these Settlement Notices, I ordered GSK to “prepare and send, at GSK’s expense, all notices that may be required by the Class Action Fairness Act of 2005 (‘CAFA’) as specified in 28 U.S.C. § 1715” (“CAFA Notice”). *Id.* at 11. CAFA requires “each defendant that is participating in [a] proposed settlement [to] serve upon the appropriate State official of each State in which a class member resides and the appropriate Federal official, a notice of the proposed settlement.” 28 U.S.C. § 1715(b). With this proposed notice, a defendant must include various documents, including the complaint, any proposed or final notification to class members, and any proposed or final class action settlement. *See id.* § 1715(b)(1)-(8).

The CAFA Notice that GSK disseminated included copies of the operative Class Action Complaint, the Settlement Agreement, and the various Settlement Notices sent to Settlement Class members. *See ECF No. 571.* Louisiana’s Attorney General received GSK’s CAFA Notice on December 27, 2012. *See ECF No. 678, Ex. A.* Louisiana did not receive a directly-mailed

Settlement Notice from Class Counsel. *See id.*, Ex. B. The State did not opt out or file any objections to the Settlement Agreement.

B. Final Approval of the Settlement Agreement

On June 19, 2013, I certified the Settlement Class³ and issued final approval for the Settlement Agreement. My Final Order and Judgment stated that, upon the Settlement Agreement becoming effective, GSK would be “released and forever discharged from all manner of claims . . . that Plaintiffs or any member or members of the Settlement Class, whether or not they object[ed] to the Settlement and whether or not they ma[de] a claim upon . . . the Settlement Fund . . . , alleged or which could have been alleged in the Actions relating to” Flonase. ECF No. 606, at 9. I also enjoined members of the Settlement Class “from commencing . . . any proceeding in any state or federal court . . . alleging or asserting” any claims against GSK that were covered by the Settlement Agreement. *Id.* at 11.

Finally, I reserved “exclusive and continuing jurisdiction” over “any suit, action, proceeding or dispute arising out of or relating to th[e] Settlement or the Settlement Agreement or the applicability or interpretation of the Settlement Agreement, or the Final Order and Judgment, including, without limitation any suit, action, proceeding or dispute relating to the Release provisions.” *Id.* at 8.

C. Louisiana’s Lawsuit and GSK’s Motion to Enforce Class Settlement

On December 29, 2014, Louisiana brought suit “in its proprietary and/or sovereign capacity” to recover for its “purchases of and reimbursements for the prescription drug Flonase and its generic equivalent, fluticasone propionate” between May 19, 2004 and February 22, 2006. ECF No. 661, Ex. A, at 1-2. The State’s complaint, which was filed in Louisiana state court,

³ The class certified in my Final Order and Judgment was the same as the class I preliminarily certified in my January 14, 2013 Order.

alleged that GSK had interfered with the FDA's drug-approval process in order "to prevent or delay a less expensive generic version of fluticasone propionate from entering the market." *Id.* at 1. As a result, Louisiana claimed, "the State paid unlawfully inflated prices for brand name Flonase when generic versions of Flonase, and the accompanying lower generic prices, would otherwise have been available." *Id.* at 2. The complaint alleged only violations of Louisiana state law. *Id.* at 19-21.

On February 4, 2015, GSK removed Louisiana's lawsuit to the Middle District of Louisiana, arguing that federal question jurisdiction existed because Louisiana's state-law claims "necessarily raised" "federal questions of law." *See Louisiana v. SmithKline Beecham Corp.*, No. 15-cv-00055, ECF No. 1, at 2 (M.D. La. Feb. 4, 2015). Louisiana moved to remand the case. *See id.*, ECF No. 5. This motion is currently pending before the Middle District of Louisiana. The Louisiana district court has stayed "all pretrial activity" and "all . . . discovery and pretrial deadlines[] pending the Court's final determination of the State's motion to remand." *Id.*, ECF No. 4.

II. DISCUSSION

On April 2, 2015, GSK filed its Motion to Enforce Class Settlement in this Court, arguing that some of the claims raised in Louisiana's lawsuit are barred by the Settlement Agreement.⁴ On April 30, 2015, Louisiana filed a motion to dismiss arguing that this Court lacks jurisdiction to enjoin Louisiana's lawsuit because the State has not waived its Eleventh Amendment sovereign immunity. Alternatively, Louisiana moves to stay proceedings until the Louisiana district court resolves the State's motion to remand. On December 1, 2015, I heard oral argument

⁴ On the same day, GSK also filed a motion in the Middle District of Louisiana seeking to transfer Louisiana's lawsuit to this Court. *See Louisiana v. SmithKline Beecham Corp.*, No. 15-cv-00055, ECF No. 8 (M.D. La. Apr. 2, 2015). The Louisiana district court, however, struck GSK's motion as a violation of its order staying pretrial proceedings. *See id.*, ECF No. 36.

on the parties' motions and ordered supplemental briefing. The briefs were filed on December 9, 2015.

I will grant Louisiana's motion to dismiss for lack of jurisdiction and deny GSK's motion to enforce the class settlement against Louisiana.⁵

A. The Eleventh Amendment and Waiver of Sovereign Immunity

The Eleventh Amendment, which precludes any suit in federal court "against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State," U.S. Const. amend. XI, reaffirms the general principle of sovereign immunity: "each State is a sovereign entity in our federal system[] and . . . [i]t is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent." *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 54 (1996) (second alteration in original). "While the Amendment by its terms does not bar suits against a State by its own citizens, th[e] [Supreme] Court has consistently held that an unconsenting State is immune from suits brought in federal courts by her own citizens as well as by citizens of another State." *Edelman v. Jordan*, 415 U.S. 651, 662-63 (1974). Sovereign immunity applies to suits for both damages and for injunctive relief, *see Cory v. White*, 457 U.S. 85, 90-91 (1982), and acts as a limit on the jurisdiction of federal courts, *see Sossamon v. Texas*, 563 U.S. 277, 284 (2011) ("Sovereign immunity principles enforce an important constitutional limitation on the power of the federal courts."); *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 98 (1984) ("[T]he fundamental principle of sovereign immunity limits the grant of judicial authority in Article III.").

"The preeminent purpose of state sovereign immunity is to accord States the dignity that is consistent with their status as sovereign entities." *Fed. Mar. Comm'n v. S.C. State Ports Auth.*,

⁵ Because I will grant Louisiana's motion to dismiss, I will not address its alternative motion to stay proceedings.

535 U.S. 743, 760 (2002); *see also Sossamon*, 563 U.S. at 283 (“Immunity from private suits has long been considered ‘central to sovereign dignity.’”’ (quoting *Alden v. Maine*, 527 U.S. 706, 715 (1999))). As the Supreme Court has recognized, the “object and purpose of the 11th Amendment [is] to prevent the indignity of subjecting a State to the coercive process of judicial tribunals at the instance of private entities.” *P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 146 (1993); *see also Fresenius Med. Care Cardiovascular Res., Inc. v. P.R. & Caribbean Cardiovascular Ctr. Corp.*, 322 F.3d 56, 63 (1st Cir. 2003) (recognizing a State’s “dignity interest as a sovereign in not being haled into federal court” (internal quotation marks omitted)). Thus, a State retains the autonomy to choose “not merely *whether* it may be sued, but *where* it may be sued.” *Halderman*, 465 U.S. at 99.

In order to preserve a State’s sovereign dignity to decide where and when to have its claims adjudicated, the Supreme Court has repeatedly emphasized that a State’s consent to suit must be “unequivocally expressed.” *Id.*; *see also Sossamon*, 563 U.S. at 284. The test for whether a State has waived its sovereign immunity “is a stringent one.” *College Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 675 (1999) (internal quotation marks omitted). “[A] waiver of sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign.” *Sossamon*, 563 U.S. at 285 (internal quotation marks omitted); *see also United States v. Nordic Village, Inc.*, 503 U.S. 30, 34 (1992) (noting “the traditional principle that the Government’s consent to be sued must be construed strictly in favor of the sovereign” (internal quotation marks omitted)).

The Supreme Court generally finds waiver “either if the State voluntarily invokes [federal court] jurisdiction, or else if the State makes a clear declaration that it intends to submit itself to [federal court] jurisdiction.” *College Sav. Bank*, 527 U.S. at 675-76 (citations omitted)

(internal quotation marks omitted). The “relevant ‘clarity’ . . . must focus on the litigation act the State takes that creates the waiver.” *Lapides v. Bd. of Regents of Univ. Sys. of Ga.*, 535 U.S. 613, 620 (2002). Once a State voluntarily “submits its rights for judicial determination,” however, it cannot “escape the result of its own voluntary act by invoking the prohibitions of the 11th Amendment.” *Gunter v. Atl. Coast Line R. Co.*, 200 U.S. 273, 284 (1906); *see also Lapides*, 535 U.S. at 619 (noting that it would be “anomalous” for a State both “to invoke federal jurisdiction” and then “claim Eleventh Amendment immunity”).

B. Louisiana Did Not Unequivocally Consent to the Settlement Agreement

GSK seeks to enjoin Louisiana from pursuing any claims covered by the Settlement Agreement. The parties agree that I retain jurisdiction to interpret the Settlement Agreement and determine who falls within the class definition. The Settlement Agreement includes States in the class definition “to the extent they purchased fluticasone propionate nasal spray (branded Flonase and/or its generic equivalents) for their employees or others covered by a government employee health plan.” ECF No. 566, Ex. 1, at 4. Thus, Louisiana falls within the Settlement Class to the extent that it purchased FP for these limited purposes. In its complaint, Louisiana seeks to recover for “all damages sustained by the State” resulting from “paying higher prices for Flonase than it would have paid in the absence of [GSK’s alleged] violations.” ECF No. 661, Ex. A, at 21-22. On its face, Louisiana’s complaint encompasses the types of claims covered by the Settlement Agreement—namely, the State’s purchases of FP for its employees and other beneficiaries of government employee health plans.⁶

⁶ Louisiana argues that its lawsuit also involves claims not covered by the Settlement Agreement, including Medicaid reimbursements and “purchases for its prisons, universities, hospitals, etc.” ECF No. 667, at 13. GSK, however, only moves to enjoin the State from seeking recovery for purchases of FP for employees and employee health plan beneficiaries, and acknowledges that Louisiana may continue to pursue its other claims against GSK. *See* ECF No. 679, Ex. A, at 11 (acknowledgment by GSK’s counsel that Louisiana has “claims [it] may assert that fall outside of the parameters of the settlement”).

Even though some of Louisiana's claims fall within the Settlement Agreement, I cannot enjoin Louisiana unless the State has waived its sovereign immunity and consented to this Court's jurisdiction. GSK claims that Louisiana's failure to opt out of the settlement constitutes consent to the Settlement Agreement and this Court's exclusive jurisdiction to enforce that Agreement. Louisiana argues that binding States as absent class members in a Rule 23(b)(3) opt-out class violates their sovereign immunity. Alternatively, Louisiana argues that even if a State could be included as an absent class member, here, Louisiana did not unequivocally consent to this Court's jurisdiction because it was not adequately notified of the Settlement Agreement. I need not—and do not—address the broader question of whether the Eleventh Amendment ever permits a State to be bound as an absent class member in a Rule 23(b)(3) opt-out class.⁷

⁷ The ability of private parties to bind States as absent class members in a Rule 23(b)(3) opt-out class is an open question of law. Several district courts have certified settlement classes that include state governments and agencies as absent class members. *See, e.g., In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, No. 04-cv-10981, ECF No. 4302, at 3 (D. Mass. Nov. 7, 2014); *S. States Police Benevolent Ass'n v. First Choice Armor & Equip.*, 241 F.R.D. 85, 93 (D. Mass. 2007); *In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75 (D. Mass. 2005). In *Southern States Police Benevolent Association*, for example, the district court specifically found that a court may “certif[y] state agencies as part of a class action,” even if they do not explicitly authorize class counsel to represent them, “so long as they are afforded the opportunity to opt out of the class.” 241 F.R.D. at 93. On the other hand, some courts have suggested that “significant sovereignty issues may preclude defining a class to include state entities as absent class members under the Eleventh Amendment of the Constitution.” *In re McKesson Gov't Entities Average Wholesale Price Litig.*, 767 F. Supp. 2d 263, 271 (D. Mass. 2011); *see also Walker v. Liggett Grp., Inc.*, 982 F. Supp. 1208, 1210-11 (S.D. W. Va. 1997) (concluding that the ability to opt out of a class was inadequate to protect a State's sovereign immunity).

Indeed, the inclusion of States as absent class members falls in a gray area of Eleventh Amendment jurisprudence. Most Eleventh Amendment cases involve suits *against* a State—i.e., attempts to hale a State into federal court as a defendant—rather than suits brought on behalf of States. At least one circuit has held that state agencies cannot be involuntarily joined under Federal Rule of Civil Procedure 19, even if the state agency would be realigned as a plaintiff, because involuntary joinder would “compel [the state agency] to act by forcing it to prosecute [its claims] at a time and place dictated by the federal courts.” *Thomas v. FAG Bearings Corp.*, 50 F.3d 502, 505 (8th Cir. 1995). But unlike involuntary joinder, which may compromise a State's dignity by forcing it to bring its claims in a particular forum, under Rule 23(b)(3) a State has the ability to opt out of a class and retain complete control of its claims. This opt-out mechanism, then, might serve “to avoid the indignity of subjecting a State to the coercive process of judicial tribunals at the instance of private parties.” *Seminole Tribe*, 517 U.S. at 58 (internal quotation marks omitted).

Assuming that Louisiana was properly included as an absent class member, the notice received by the State was insufficient to meet the “stringent” test for determining whether it “voluntarily” and “unequivocally” agreed to have its claims resolved through the Settlement Agreement.⁸

The parties agree that the only notice Louisiana received was the CAFA Notice. A CAFA Notice is sent to the “appropriate official of each State in which a class member resides.”²⁸ U.S.C. § 1715(b). Whether a CAFA Notice is sent to a State depends on if its citizens are impacted by the settlement, and not on the State’s membership in the class. A court cannot give final approval to a proposed settlement until ninety days after the appropriate state officials receive the CAFA Notice. *Id.* § 1715(d). This ninety-day period is meant to allow States “to review the proposed settlement and decide what (if any) action to take to protect the interests of the plaintiff class.” S. Rep. No. 109-14, at 35, 2005 WL 627977, at *34 (2005).

By notifying States about class actions impacting their citizens, the CAFA Notice is “intended to give states a role in ensuring that [their] citizens are equitably compensated in class action settlements.” *California v. Intelligender, LLC*, 771 F.3d 1169, 1173 (9th Cir. 2014); *see id.* at 1172 (noting that “CAFA expressly provides that the defendant in a class action must provide notice to the appropriate state official of any proposed settlement, presumably so that the state may comment upon or object to the settlement’s approval, if the State believes the terms

Nevertheless, it is unclear whether the ability to opt out of a class necessarily preserves a State’s sovereign immunity in *every* case. For example, neither Rule 23 nor the Due Process Clause requires that class members receive actual notice of a class action. *See* 4 Alba Conte, *Newberg on Class Actions* § 11:53 (4th ed. 2002). Thus, “an absent class member will be bound by any judgment that is entered if appropriate notice is given, even though the absentee never actually received notice.” 7AA Wright et al., *Federal Practice & Procedure* § 1789.1, at 571 (3d ed. 2005). This ability to bind absent class members, even when they do not have actual notice of the class action or their ability to opt out, would hardly appear to satisfy the Supreme Court’s “stringent” test for determining whether a sovereign State has “unequivocally” waived its sovereign immunity. *Sossamon*, 563 U.S. at 284 (internal quotation marks omitted).

⁸ I only address the adequacy of notice as it relates to the Eleventh Amendment’s high standard for waiver of sovereign immunity. I previously approved the adequacy of notice in this case for purposes of Rule 23. *See* ECF No. 606, at 3.

inadequately protect state citizens"). The legislative history of § 1715 further confirms that Congress intended the CAFA Notice to enable States to safeguard their citizens' interests, rather than their own. For example, the Senate Judiciary Committee Report states that § 1715 provides an "additional mechanism to safeguard plaintiff class members' rights by requiring that notice of class action settlements be sent to appropriate state and federal officials, so that they may voice concerns if they believe that the class action settlement is not in the best interest of their citizens." S. Rep. No. 109-14, at 5; *see also id.* at 35 ("[N]otifying appropriate state and federal officials of proposed class action settlements will provide a check against inequitable settlements in these cases."). *See generally* Catherine M. Sharkey, *CAFA Settlement Notice Provision: Optimal Regulatory Policy*, 156 U. Pa. L. Rev. 1971 (2005) (discussing the enactment of § 1715 and its effect on state attorneys generals' ability to protect citizen class members).

Thus, the CAFA Notice that GSK sent to Louisiana alerted the State to the fact that some of its citizens would be affected by the Flonase Settlement. *See* ECF No. 571 (indicating that approximately 166,421 consumer class members and 246 third-party payor class members resided in Louisiana). GSK points out that the Settlement Agreement and the Settlement Notices were attached to the CAFA Notice, and thus argues that Louisiana should have been aware that it was included in the class. It is certainly possible that the State could have learned that it was included as a class member by reviewing the Settlement Agreement attached to the CAFA Notice. But given the purpose of the CAFA Notice, it is just as likely that Louisiana would have considered these documents with a view to protecting the interests of its citizens. In short, it is not clear that upon receipt of the CAFA Notice, Louisiana would have been aware that the State itself was a class member and that, if it did not opt out, it would be bound by the Settlement Agreement.

This lack of clarity is fatal to GSK's argument that Louisiana's failure to opt out after receiving the CAFA Notice constitutes consent to this Court's jurisdiction. The test for finding a waiver of sovereign immunity is stringent, and ambiguities are resolved in favor of the sovereign. Here, Louisiana's receipt of the CAFA Notice is insufficient to unequivocally demonstrate that the State was aware that it was a class member and voluntarily chose to have its claims resolved by the Settlement Agreement.

III. CONCLUSION

Louisiana has not clearly waived its sovereign immunity. Therefore, I will grant Louisiana's Motion to Dismiss (ECF No. 667) and deny GSK's Motion to Enforce Class Settlement (ECF No. 661) because this Court lacks the authority to enjoin the State from pursuing its lawsuit against GSK.

s/Anita B. Brody

ANITA B. BRODY, J.